K131787

Keeler
Ophthalmic Instruments

DEC 2 3 2013

510(k) Summary of Safety and Effectiveness

1. Submitter Name and Address

Keeler Instruments Inc
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Date Prepared: April 2013 (revised December 2013)

2. Device Name (Unmodified)

Trade Name:	Cryomatic System and Probes
Common/Usual Name:	Cryophthalmic Surgical System and Probes
Classification Name:	Unit, Cryophthalmic, AC-powered
Regulation No:	886.4170
Device Regulatory Class:	II
Product Code:	HRN
Review Panel:	Ophthalmic
510(k) Number:	K062412 & K112093

3. Proposed Modification

The proposed modification described in this Special 510(k) covers the simplification of the coupling mechanism to accept both Keeler Cryomatic disposable and re-useable probes without the use of a special adaptor.

Since the launch of the Keeler Cryomatic System , a disposable version of the Retinal Probe has become available which has a different interface connection than that of the Keeler Re-usable Probe range which resulted in Keeler developing an adaptor so that the disposable variant could be connected to the console.
The modification has simplified the probe coupling system. It is a safe, quick release coupling that accepts both the Keeler range of modified re-useable probes and Keeler disposable probes (unchanged), without the need for a special adaptor.

The intended use of the Keeler Cryomatic System and Probes is unchanged following the introduction of the new coupling mechanism. The control of the freeze and defrost functions is the same as that for the current Keeler range of non-disposable probes.

4. Device Description

Console

The Cryomatic MKII console is a self-contained system. The console consists of a rigid PU enclosure, housing the principle subsystems, switch mode power supply, controller PCB and pneumatic control module. On the front of the console is an LCD screen and membrane key panel. The console provides the connection point for the range of probe (reusable and disposable), footswitch, mains electricity, gas supply and scavenging system.

Cryomatic Probes

There is a variety of Keeler Re-usable Cryomatic Probes whose stainless tips are shaped depending on surgical application. The plastic handle is permanently connected to flexible pressure hose and integral connector, which connects to Cryomatic MKII Console.
The Keeler Disposable Cryo Probe comprises a stainless steel stem with a metal handle connected to a 2m long bi-lumen high-pressure plastic hose contained within a protective outer tube and terminated with a custom-designed plastic connector for insertion into the Cryomatic MKII console.

Method of Operation

When the footswitch is pressed, high pressure cryogen gas is circulated through the Cryo probe, rapid gas expansion in the probe tip causes freezing according to the Joule-Thompson principle. This gas supply to the probe tip is controlled using solenoid valves interconnected via an arrangement of galleries in a manifold.

The system displays user information by means of a graphical LCD on the front panel. All relevant information such as operating state, warnings, condition of gas cylinder and any fault information is displayed in an unambiguous fashion.

5. Labeling and Intended Use

Instructions for use (IFU) for the Keeler Cryomatic System have been updated to incorporate the use of the new coupling mechanism.

A separate reusable probe IFU will no longer be supplied with each probe as is currently the case. Instead a copy of the IFU supplied with the console will be supplied with the probes.

Console labels have been updated to identify the MKII model, and packaging labels for the reusable probes have been updated with revised part numbers of the modified versions.

The IFU for the disposable probes has also been updated to reference the new Cryomatic System.

The intended use of the Keeler Cryomatic System & Probes (including the disposable probe) is the same as originally cleared under the original 510(k) premarket notifications (K062412 &K112093).

6. Materials Biocompatibility

With respect to materials that come into direct contact intentionally with the eye during surgery, there are no changes. In both types of probe, the exposed stem is made of stainless steel with a smooth welded tip. This tip is formed by electron beam welding utilizing the parent material, which does not require addition of any other materials such as flux or weld filler.

7. Sterilization and Shelf Life

The Sterilization method (pre-sterilised with ethylene oxide gas) for the single use Disposable Cryo Probes is unchanged.

The recommended method for sterilizing re-usable probes is steam sterilization, which remains unchanged. As the design of the re-usable probes has changed, validation of the steam sterilization process was carried out to demonstrate that the sterilization parameters outlined in the instruction for use are sufficient to sterilize the modified probes.

8. Comparison of the device with the Predicate

The comparison table below summarizes the similarities and differences between both systems, with respect to safety and effectiveness, which are discussed in more detail in the following sections.

Characteristic Features	Modified Device	Cryomatic System and Probes	Notes
General Arrangement	Desktop console with Optional trolley	Desktop console with Optional trolley	No change
Cryogen Type	CO^2 or N2O	CO^2 or N2O	No change
Single cylinder connection	Yes	Yes	No change
Freeze system pressure regulation	Automatic	Automatic	No change
Freeze control	Footswitch	Footswitch	No change

Purge Cycle	Manual	Automatic	Purge cycle is not required for the disposable probe, user initiates the purge cycle for reusable probes. The purge cycle is intended to remove any debris left in the reusable probes following the sterilization process. The modification does not affect the safety or effectiveness of the device
Auto-clean	Yes	Yes	No change
Audible Indicator	Yes	Yes	No change
Cryo-probe connection mechanism	Quick release	Quick release Console – 2 male plugs Probes – 2 female plug sockets	The coupling mechanism has been updated to accommodate both disposable and reusable probes. The modification does not affect the safety or effectiveness of the device
Disposable probe connection	No adaptor required	Connected to the console via disposable probe adaptor	The coupling mechanism has been updated to accommodate both disposable and reusable probes. The modification does not affect the safety or effectiveness of the device

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Instruction for Use (IFU)	The IFU (Part # EP59-11410) has been updated to include instructions on how to operate the new coupling mechanism, new graphics have been added to the symbols section, the list of probes used with the devices has been updated to reference the modified probe part numbers as well the disposable probes and the Trouble Shooting section has been updated.	IFU supplied with the console (Part # 2509-P-8012) The list of probes used with the Cryomatic Console does not reference the disposable probe	The intend use of the device has not changed The modifications do not affect the safety or effectiveness of the device
Instruction for Use (IFU)	IFU (part # EP59-11410) supplied with the console and the probes	IFU supplied with the console (part # 2509-P-8012) IFU supplied with probes (part # KCU402)	The IFU (part # EP59-11410) contains all the information needed to safely operate and console and probes
Disposable probe IFU (Part # 2508-P-7022)	IFU (Part # EP59-41003) updated to approve use with modified console. For use only with the Keeler Disposable Probe Adapter (2508-P-8026) and Cryomatic Console (2509-P-1000) or the Cryomatic MKII Console (2509-P-1010)	For use only with the Keeler Disposable Probe Adapter (2508-P-8026) and Cryomatic Console (2509-P-1000)	Allows use with the modified console
Freeze Zone	End freeze	End freeze	No change
Construction	Stainless steel (Electron beam welding)	Stainless steel (Electron beam welding)	No change
Probe range -	Full range of ophthalmic probes	Full range of ophthalmic probes	No change
Electrical supply	mains	mains	No change

Control system	Embedded micro-controller (embedded software)	Embedded micro-controller (embedded software)	Software has been updated to incorporated changes to the coupling mechanism The modification does not affect the safety or effectiveness of the device
Sterilization	Pre-vacuum (porous load) 134 – 137 °C (273-279 °F) 3 minutes Pre-vacuum (porous load) 134 – 137 °C (273-279 °F) 18 minutes	Pre-vacuum (porous load) 134 – 137 °C (273-279 °F) 3 minutes Gravity 121-124 °C (250-255 °F) 30 minutes	No requirement to have two methods of sterilization. The sterilization methods have been validated The modification does not affect the safety or effectiveness of the device

9. Performance and Safety

Verification tests have been carried out to confirm that the cryogenic performance and safety aspects of the modified console and probes are comparable with the Keeler Cryomatic System and Probes cleared for marketing under 510(k) K062412 and K112093.

These verification tests evaluated the following aspects:

a) Probe external temperature and repeatability
b) Iceball growth capability
c) Defrost performance
d) Tractive power

The modified Keeler Cryomatic System and probes have been evaluated against the requirements of IEC 60601-1 for electrical safety and to IEC 60601-1-2 for electromagnetic compatibility.

In all tests the modified device was in compliance with these FDA recognized standards.

10. Substantial Equivalence

The modified Keeler Cryomatic System and Probes (Keeler Cryomatic MKII System), is considered to be substantially equivalent to the Cryomatic System and Probes described in the original 510(k) submissions (K062412 &K112093).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

Keeler Instruments, Inc.
Mr. Eugene R. Van Arsdale
Marketing Manager
456 Parkway
Broomall, PA 19008-4295

Re: K131787
Trade/Device Name: Cryomatic MKII Console, Cryomatic MKII Probes, Disposable Cryo Probes
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic Unit
Regulatory Class: Class II
Product Code: HRN
Dated: November 25, 2013
Received: November 26, 2013

Dear Mr. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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2. Indications for Use Statement

510(k) Number (if known): K131787

Device Name: Keeler Cryomatic MKII Cryosurgical System.

Indications for Use:

The Keeler Cryomatic System and probes are for use in ophthalmic surgery such as cryopexy for retinal detachment, cyclo destructive procedures in refractory glaucoma, extraction of fragments within the vitreous cavity, cataract extraction, cryo destruction of lash follicles for trichiasis and treatment of retinopathy of prematurity (ROP).

Prescription Use _√_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles Chiang -S
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